IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

UNITED STATES OF AMERICA	§	
***ex rel.* LESLIE STEURY**	§	
	§	
v.	§	**CIVIL ACTION NO. H-07-1705**
	§	
CARDINAL HEALTH, INC.	§	
F/K/A ALARIS MEDICAL SYSTEMS, INC.;	§	
CARDINAL HEALTH 303, INC.	§	
F/K/A ALARIS MEDICAL SYSTEMS, INC.;	§	
CARDINAL HEALTH SOLUTIONS, INC.	§	**JURY TRIAL DEMANDED**

PLAINTIFF'S THIRD AMENDED COMPLAINT

Plaintiff United States of America *ex rel*. Leslie Steury files its Third Amended Complaint against Defendants Cardinal Health, Inc. f/k/a Alaris Medical Systems, Inc.; Cardinal Health 303, Inc. f/k/a Alaris Medical Systems, Inc.; and Cardinal Health Solutions, Inc. (collectively, "Cardinal Health"). Steury, the *qui tam* relator, brings this False Claims Act lawsuit under 31 U.S.C. §§ 3729-3732 on behalf of the United States.

I. Parties

1. Relator Leslie Steury is a citizen of the United States and a resident of the State of Texas.

2. Defendant Cardinal Health, Inc., formerly known as Alaris Medical Systems, Inc., is an Ohio corporation. It has been served and appeared.

3. Defendant Cardinal Health 303, Inc., formerly known as Alaris Medical Systems, Inc., is a California corporation. It has been served and appeared.

4. Defendant Cardinal Health Solutions, Inc. is a California corporation. It has been served and appeared.

II. Jurisdiction

5. This Court has jurisdiction under 31 U.S.C. § 3730(b)(1) and 31 U.S.C. § 3732 because this is a False Claims Act case brought by a private person in the name of the United States.

III. Venue

6. Venue is proper in this District under 31 U.S.C. § 3730(b)(l) and 31 U.S.C. § 3732(a) because Cardinal Health is qualified to do business in this District and because it committed acts proscribed by 31 U.S.C. §§ 3729 in this District.

IV. Background

7. This is a False Claims Act suit related to Cardinal Health's sale of defective intravenous ("IV") infusion pumps to the United States Department of Veterans Affairs (the "VA").

A. The SE Infusion Pump had a defect that made it dangerous to use

8. From 1997 to August 2006, Cardinal Health—and its predecessor Alaris Medical Systems, Inc. ("Alaris")—sold the Signature Edition Infusion Device (the "SE infusion pump") to VA hospitals.[1] The SE infusion pump was designed to deliver a wide variety of fluids, including medicine, over a broad range of infusion rates to patients. The purpose of the device was to regulate and control the rate at which fluid flowed into patients. It was a programmable box that attached to IV poles.

9. The SE infusion pump had a defect that made it unsafe. The pump had disposable silicone tubing—called the Accuslide—that the fluids flowed through. The pump's motor squeezed the Accuslide in order to control the IV flow rate into the patient. The way that the Accuslide worked with the pump allowed excessive—and unsafe levels of—air bubbles to collect. These air

[1] Cardinal Health purchased Alaris on July 7, 2004. References to Cardinal Health before that date refer solely to Alaris.

bubbles were then injected into the patient's IV line. It is potentially deadly for air bubbles to enter a patient's veins through an IV.

10. The SE infusion pump is a rectangular-shaped electronic device that consists of a programming panel to control software, as well as two chambers on the left and right side of the panel

into which the Accuslide slips. The software controls the movement of the motor feet within the chamber, which massage the tubing within the Accuslide to establish a controlled rate of flow of intravenous fluid into a patient. The Accuslide is a disposable tubing set, allowing a new tubing set to be used for each patient.

11. The Accuslide, which fits into the main component of the SE infusion pump, consists of two axial halves, which fit together. Embedded into each half of the Accuslide is one half of silicone tubing, as if the silicone tubing had been cut in half. Projecting from each half of the Accuslide is tubing made from polyvinylchloride ("PVC") that leads either to the patient or to the bag containing the fluid to be pumped intravenously into the patient. In other words, the Accuslide is like a box that has been cut in half to display its contents.

12. The tubing embedded in the Accuslide is made from silicone, which is a softer and more permeable piece of tubing than PVC. Silicone is used in order to prevent memory retention during motor movement when the silicone tubing is exposed to the motor within the SE infusion pump. In addition, silicone does not degrade over time like PVC. Because of its permeability, however, the silicone allows air to move into the tubing. In addition, the motor feet on the pump are round, permitting air to accumulate between the motor feet.

13. Because the two pieces of the Accuslide fit together, the silicone tubing embedded in the Accuslide does not create a perfectly round-in-circumference tube through which the fluid flows. Instead, there are "square eddy" channels along the inside diameter of the

tubing. These "square eddy" channels are formed in the gap between the two axial halves of the silicone tubing embedded in both sides, front and back, of the Accuslide. The air that permeates into the silicone tubing and between the round motor foot is then collected in these square eddies as the fluid is moved along the tube. This causes the trapped air to grow into a large air bubble that eventually releases and travels down the tubing set to the patient, rather than up the tubing set and into the intravenous bag.

14. The SE infusion pump was the only IV infusion pump on the market at the time that had a square-eddy design. This square-eddy design caused the SE infusion pump to infuse patients with air bubbles to a much greater degree than other IV infusion pumps—which did not have the square-eddy design. This includes other pumps made by Cardinal Health, as well as pumps made by competitors. While IV infusion pumps without the square-eddy design could, on occasion, allow small air bubbles to collect and be infused into patients, the amount of air bubbles using the square-eddy design was much greater. Therefore, the SE infusion pump—with its square-eddy design—caused air-bubble levels that far exceeded the average, fair, or medium-grade quality infusion pump on the market. This made the SE infusion pump of less than average, fair, or medium-grade quality as compared to other similar devices. For example, testing by the end of May 2001 of Cardinal Health's Gemini infusion pump[2] showed that it did not deliver any air into the patient, while testing of the SE infusion pump showed that under normal conditions it delivered between 10 ml and 26 ml of air into the patients. These are dangerous levels of air that could injure or kill patients.

15. The SE infusion pump—like most infusion pumps—was equipped with an air-in-line detectors, which alerts the healthcare professional to the presence of an air bubble in the fluid. The

[2] The performance of the Gemini infusion pump was comparable to other infusion pumps on the market at the time the SE infusion pump was developed and sold. The performance of the Gemini pump—in general and specifically regarding air in the lines—was approximately the same as similar pumps manufactured by other companies at the time. The Gemini infusion pumps represent the type of infusion pumps against which the SE infusion pump would be compared in the market.

air-in-line detector is an infrared sensor that measures air passing through the fluid in the intravenous tubing moving towards the patient. While the air-in-line detector's main purpose is to detect when the intravenous bag runs dry, its second purpose is to detect air bubbles as they pass in the intravenous tubing. The air-in-line detector is the final effort to detect the air bubble in the fluid before entering the patient. Air-in-line detectors do not catch all air bubbles, however, so they are not sufficient protection for patients if the IV infusion pump creates large numbers of air bubbles. Therefore, given the large volume of air bubbles that the SE infusion pump's square-eddy design created, the air-in-line detector was not sufficient protection for patients.[3]

16. The SE infusion pump provided no significant advantage to offset the heightened risk of air in the line. There was no particular basis for preferring the SE device over similar devices that would justify accepting the risk of patient injury or death that would result from the air-in-line problem.

17. The SE infusion pumps had a serious defect because the square-eddy design allowed excessive air to enter the intravenous line and go into the patient. Every SE infusion pump contained this defect, because it was a defect based on the square-eddy design, as opposed to a manufacturing defect that would only appear in some units. Serious health dangers—including death and serious injury—can occur when air enters a patient's bloodstream.

B. Cardinal Health knew about the dangerous defect

18. From March 18, 1996, until September 28, 2001, Steury worked for Cardinal Health[4] as an Account Consultant marketing medical devices, including the SE infusion pump, to VA

[3] Steury is not alleging that the SE infusion pump's air-in-line detector was defective. The SE infusion pump's air-in-line detector was of the same quality as the air-in-line detectors on the average infusion pumps. Instead, Steury is alleging that the square-eddy defect in the SE infusion pump created such a large quantity of air bubbles that it overwhelmed the air-in-line detector.

[4] As discussed above, Cardinal Health was known as Alaris at this time.

hospitals (as well as other hospitals). In 1997, Steury began working for Cardinal Health in the Cleveland, Ohio area.

19. In her capacity as a Cardinal Health Account Consultant, Steury learned about the SE infusion pump's dangerous square-eddy/air-in-line defect. And, in that same capacity, Steury learned about Cardinal Health's knowledge of the defect.

20. In November 2000, a doctor warned Cardinal Health employees that the SE infusion pump had injected air into his patient's IV line. Specifically, Dr. Mark DiLuciano, a pediatric anesthesiologist at Children's Hospital of Akron, Ohio, told Cardinal Health Manager of Clinical Consultants Susan Springman about this event.

21. In May 2001, a nurse at Children's Hospital of Akron, Ohio told Steury that a baby had died when the SE infusion pump injected air into her IV line. Steury immediately told Cardinal Health's management about the death.[6] Cardinal Health's management responded by denying that air in the line caused the baby's death.

[6] Steury told, at least, Cardinal Health Ohio Valley Area Manager John Snow, Cardinal Health Eastern Director of Sales Joe Vollero, Cardinal Health National Accounts Manager Cathy Larson, Cardinal Health Manager of Clinical Consultants Susan Springman, Cardinal Health Manager of Field Support Services Marianne Gill, Cardinal Health Ohio Valley Region Clinical Consultant Tonya Vick, and Cardinal Health Director of Medication Management Systems Tim Vanderveen. As Cardinal Health Ohio Valley Area Manager, John Snow was responsible for sales and implementation of all Cardinal Health products in a multi-state region that included at least Ohio, Indiana, West Virginia, and Pennsylvania. He supervised at least five sales people. As Cardinal Health Eastern Director of Sales, Joe Vollero supervised all Eastern Region area managers, including Snow. The country was divided into regions, with states east of the Mississippi River being in the Eastern Region. This was a senior executive management position with Cardinal Health. As Cardinal Health Manager of Clinical Consultants, Susan Springman was in charge of all Cardinal Health nurses. Those nurses provided education, training, and implementation of Cardinal Health products (including the SE infusion pump) for hospitals. As Cardinal Health Manager of Field Support Services, Marianne Gill was a liaison between Cardinal Health corporate headquarters and Cardinal Health's nurses in the field. As Cardinal Health Ohio Valley Region Clinical Consultant, Tonya Vick was a nurse who provided education, training, and implementation of Cardinal Health products (including the SE infusion pump) for hospitals in Cardinal Health's Ohio Valley Region. As Cardinal Health Director of Medication Management Systems, Tim Vanderveen—who was a pharmacist with a doctorate degree—acted as a liaison between Cardinal Health's engineering and research departments and its customers regarding Cardinal Health products, including the SE infusion pump.

22. In late May 2001, Cardinal Health management had determined that the SE infusion pump's square-eddy design was causing the excess air in the lines.[8] At a meeting that Steury attended in late May 2001, Cardinal Health Director of Medication Management Systems Tim Vanderveen drew a diagram showing the square-eddy design and explained that it was causing the excess air in the lines. Also present at that meeting were Cardinal Health Ohio Valley Area Manager John Snow, Cardinal Health Eastern Director of Sales Joe Vollero, Cardinal Health Manager of Field Support Services Marianne Gill, and Cardinal Health Director of Regulatory Affairs Bill Murphy.

23. In June 2001, Cardinal Health Ohio Valley Area Manager John Snow told Steury that Cardinal Health had temporarily stopped shipping the SE infusion pump while it reviewed the problem. Snow told Steury at that time that there should be an answer within three months. Cardinal Health continued to market the pump during the review period, however. During the three-month review period, Cardinal Health continued to receive additional reports of air-in-line problems with the SE infusion pump.

24. On June 26, 2001, Cardinal Health Director of Medication Management Systems Tim Vanderveen sent an email discussing his visit to Children's Hospital of Akron, Ohio—the hospital where the baby had died. Vanderveen said that "[t]he weekend was 'hell' from an air

[8] Specifically, Plaintiff was aware that at least Cardinal Health Ohio Valley Area Manager John Snow, Eastern Director of Sales Joe Vollero, National Accounts Manager Cathy Larson, Cardinal Health Manager of Clinical Consultants Susan Springman, Manager of Field Support Services Marianne Gill, Ohio Valley Region Clinical Consultant Tonya Vick, and Director of Medication Management Systems Tim Vanderveen knew about the defect and the danger it posed.

[10] *See* Ex. C to First Amended Petition (Doc. 23).

standpoint."[10] He made that statement in reference to the excess air in the lines caused by the square-eddy design.

25. In September 2001—at the end of the three-month review period—Cardinal Health fired Steury. Days after it fired her, Cardinal Health sold 500 SE infusion pumps to the VA hospital in Cleveland. At that time, the fact that the SE infusion pump had the square-eddy design, which caused dangerous levels of air in the IV lines, was known to at least the following Cardinal Health employees: Cardinal Health Ohio Valley Area Manager John Snow, Cardinal Health Eastern Director of Sales Joe Vollero, Cardinal Health National Accounts Manager Cathy Larson, Cardinal Health Manager of Clinical Consultants Susan Springman, Cardinal Health Manager of Field Support Services Marianne Gill, Cardinal Health Ohio Valley Region Clinical Consultant Tonya Vick, Cardinal Health Account Executive Andrew D'Acenzo, Cardinal Health Nurse Tammy Saunders, and Cardinal Health Director of Medication Management Systems Tim Vanderveen. All of those Cardinal Health employees appreciated the danger that the SE infusion pump posed. Those Cardinal Health employees knew that the SE infusion pump was, because of the air-in-line defect, not of at least average, fair, or medium-grade quality and was not comparable to other similar infusion pumps on the market. Those Cardinal Health employees knew that if the VA knew about the air-in-line defect caused by the square-eddy design, the VA would not accept—nor pay for—the SE infusion pumps.

26. Cardinal Health continued to sell the SE infusion pump to the VA, and others, for years after it learned of the air-in-line defect. In fact, Cardinal Health sold the SE infusion pump until 2006. And it was another defect—not the air-in-line defect—that caused Cardinal Health to finally quit selling the SE infusion pump.[11]

[11] In August 2006, the FDA recalled the SE infusion pumps for issues related to a design defect that cause overinfusion of medicine into the patients' bloodstream. *See* http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm062837.htm.

C. Cardinal Health sold the defective SE infusion pumps to the VA without disclosing the defects, and the VA testing did not identify the defects

27. Cardinal Health had a contract with the VA regarding the purchase of the SE infusion pumps. Each particular order of SE infusion pumps was done through a purchase order that was pursuant to the general contract. Cardinal Health sold SE infusion pumps to the VA Hospitals throughout the country—including VA hospitals in Houston, Texas and Cleveland, Ohio—under this contract.[12]

28. In this contract that Cardinal Health had with the VA regarding the SE infusion pumps, Cardinal Health expressly warranted that the SE infusion pumps were "merchantable." This was a standard condition in Cardinal Health's contracts with the VA.

29. On October 5, 2001, Cardinal Health sold 500 SE infusion pumps to the VA Cleveland Hospital through a purchase order under the contract. By this date, Cardinal Health was aware that the SE infusion pumps had the dangerous defect described above.[13] Because of the defect, the SE infusion pumps were not merchantable—that is, they were not reasonably fit for the ordinary purposes for which such items are used. Cardinal Health knew that the pumps injected more air than comparable pumps available in the market, and that the air-in-line defect rendered the product dangerous. Cardinal Health, therefore, knew the SE infusion pump was not merchantable, yet sold them to the VA anyway.

30. The VA was not aware of the SE infusion pump's air-in-line defect or its square-eddy design. The VA did limited testing on the SE infusion pumps before accepting them and

[12] Cardinal Health was by far the largest supplier of infusion pumps to the VA, and the fact that Cardinal Health sold the SE infusion pump to the VA was well known within Cardinal Health. Every Cardinal Health executive involved with the SE infusion pump knew that the company was selling that pump to the VA.

[13] As described above, Cardinal Health knew this based on the knowledge of at least the following Cardinal Health employees: Cardinal Health Ohio Valley Area Manager John Snow, Cardinal Health Eastern Director of Sales Joe Vollero, Cardinal Health National Accounts Manager Cathy Larson, Cardinal Health Manager of Clinical Consultants Susan Springman, Cardinal Health Manager of Field Support Services Marianne Gill, Cardinal Health Ohio Valley Region Clinical Consultant Tonya Vick, Cardinal Health Account Executive Andrew D'Acenzo, Cardinal Health Nurse Tammy Saunders, and Cardinal Health Director of Medication Management Systems Tim Vanderveen.

providing them to the veterans it was treating. The VA relied on Cardinal Health's testing that the SE infusion pumps—as a group—were safe and performed as represented. The VA's testing focused on making sure that the individual infusion pumps that it bought were not broken. The VA's testing was limited to making sure that each unit turned on and that its air-in-line detector worked. The VA did not do any testing to determine whether the SE infusion pumps would introduce unacceptably large quantities of air into the patient. The VA's testing was not designed to find—and would not have found—the additional air in the line that the SE infusion pump's square-eddy defect caused. Therefore, unless Cardinal Health had told the VA that its SE infusion pump caused the air-in-line problems, the VA's testing would not have uncovered it. Cardinal Health did not tell the VA about the problem.

D. Cardinal Health was aware that the SE infusion pumps were not merchantable, but sold them to the VA anyway

31. Cardinal Health's contract with the VA specifically required that the SE infusion pumps be merchantable.

32. To be merchantable, goods must meet several requirements. Failure to comply with any one of these requirements makes goods unmerchantable. These requirements are:

a. The product must be reasonably fit for the ordinary purposes for which such item is used;[14]

b. The product must be of at least average, fair, or medium-grade quality and must be comparable in quality to those that will pass without objection in the trade or market for items of the same description;[15] and

c. The product cannot be unreasonably dangerous.[16]

---

[14] 48 C.F.R. § 12.404(a)(1).

[15] *Id*.

[16] *See Gumbs v. Int'l Harvester, Inc*., 718 F.2d 88, 95 (3d Cir. 1983) ("we can conceive of no theory under which the allegedly defective [product] could have been defective and unfit for its ordinary purposes under [U.C.C.] section 2-314 but not also defective and unreasonably dangerous within [Restatement of Torts (Second)] section 402A"); 3 LARRY LAWRENCE, ANDERSON ON THE UNIFORM COMMERCIAL CODE § 2-314-720 (3d ed.); *see also* U.C.C. § 2-314(2) ("Goods to be merchantable must be at least such as: (a) pass without objection in the trade under the contract

33. The SE infusion pump was not merchantable when it was sold to the VA because:

a. The SE infusion pump was not reasonably fit for the ordinary purposes for which such item is used.[17] The ordinary purpose of an infusion pump is to infuse medicine into a patient through an IV line without endangering the patient's health or life. The SE infusion pump's square-eddy design caused it to infuse dangerous amounts of air bubbles into patients. This rendered the SE infusion pump not reasonably fit to infuse medicine into an IV line without endangering the patient's health or life.

b. The SE infusion pump was not of at least average, fair, or medium-grade quality, and was not comparable in quality to those that will pass without objection in the trade or market for items of the same description.[18] The other infusion pumps on the market did not have the square-eddy design that infused dangerous amounts of air bubbles into patients' veins. This includes the other infusion pumps manufactured by Cardinal Health, as well as the other infusion pumps manufactured by competitors. The average, fair, or medium-grade quality infusion pump on the market may have caused the occasional air bubble to be created and go into the patient, but it was not of a quantity sufficient to be highly dangerous. If Cardinal Health had disclosed to the market the facts that it knew about its square-eddy design causing large amounts of air bubbles to be infused into the patient, then it would not have passed without objection in the trade or market for IV infusion pumps. Instead, had a hospital—the average purchaser of IV infusion pumps—known of the square-eddy design and its consequences, it would have refused to purchase the SE infusion pump. That is because an average hospital would not have wanted to buy an infusion pump that greatly increased the chance that dangerous levels of air would be injected into its patients, potentially killing them. The average hospital would have chosen to buy the infusion pump that did not contain a defect inherent in every pump that could kill its patients.

---

description; and (b) in the case of fungible goods, are of fair average quality within the description; and (c) are fit for the ordinary purposes for which such goods of that description are used; and (d) run, within the variations permitted by the agreement, of even kind, quality and quantity within each unit and among all units involved; and (e) are adequately contained, packaged, and labeled as the agreement may require; and (f) conform to the promise or affirmations of fact made on the container or label if any.").

[17] 48 C.F.R. § 12.404(a)(1).

[18] *Id.*

c. The SE infusion pump was unreasonably dangerously defective due to its square-eddy design which caused it to infuse dangerous amounts of air bubbles into the patients.[19]

Although all three conditions were present, each condition independently made the SE infusion pump unmerchantable.

34. As of October 1, 2001, at least the following Cardinal Health employees were aware that the SE infusion pumps that Cardinal Health was selling to the VA were not merchantable because of the square-eddy design that caused excessive air in the line: Cardinal Health Ohio Valley Area Manager John Snow, Cardinal Health Eastern Director of Sales Joe Vollero, Cardinal Health National Accounts Manager Cathy Larson, Cardinal Health Manager of Clinical Consultants Susan Springman, Cardinal Health Manager of Field Support Services Marianne Gill, Cardinal Health Ohio Valley Region Clinical Consultant Tonya Vick, Cardinal Health Account Executive Andrew D'Acenzo, Cardinal Health Nurse Tammy Saunders, and Cardinal Health Director of Medication Management Systems Tim Vanderveen.

35. As of October 1, 2001, at least the following Cardinal Health employees were aware that Cardinal Health was selling the 500 SE infusion pumps to the VA Cleveland Hospital that were sold on October 5, 2001: Cardinal Health Ohio Valley Area Manager John Snow, Cardinal Health Eastern Director of Sales Joe Vollero, Cardinal Health National Accounts Manager Cathy Larson, Cardinal Health Manager of Clinical Consultants Susan Springman, Cardinal Health Ohio Valley Region Clinical Consultant Tonya Vick, and Cardinal Health Director of Medication Management Systems Tim Vanderveen. These Cardinal Health employees were aware that the VA required that

[19] The Federal regulations' definition of merchantable goods is, essentially, the same as the Uniform Commercial Code definition. *See* U.C.C. § 2-314(2). A product that is defective and unreasonably dangerous under products-liability law is necessarily unmerchantable. *See Gumbs v. Int'l Harvester, Inc.*, 718 F.2d 88, 95 (3d Cir. 1983) ("we can conceive of no theory under which the allegedly defective [product] could have been defective and unfit for its ordinary purposes under [U.C.C.] section 2-314 but not also defective and unreasonably dangerous within [RESTATEMENT OF TORTS (SECOND)] section 402A"); 3 LARRY LAWRENCE, ANDERSON ON THE UNIFORM COMMERCIAL CODE § 2-314-720 (3d ed.).

the SE infusion pumps that it bought be merchantable. These Cardinal Health employees were aware that SE infusion pump was not merchantable because the square-eddy design caused dangerously excessive levels of air in the line.

36. The SE infusion pump was worthless to the VA because—when used as intended—there was a high risk that it could kill patients due to its air-in-line defect. An infusion pump that kills patients when used as intended is of no value to the hospital that is using it. Instead, the infusion pump actually has a negative value because it will create tort liability for the hospital, given its defective condition.

V. Cause of Action—Violation of the False Claims Act

37. Steury adopts by reference all previous paragraphs as if set out fully here.

38. Cardinal Health violated the False Claims Act because it "knowingly present[ed], or cause[d] to be presented, a false or fraudulent claim for payment or approval" and/or it "knowingly ma[d]e, use[d], or cause[d] to be ma[d]e or use[d], a false record or statement material to a false or fraudulent claim."[20]

39. The elements of a False Claims Act violation are met here because:

- There was a false statement or fraudulent course of conduct;
- Made or carried out with the requisite scienter;
- That was material; and
- That was presented to the government.[21]

40. The required scienter is met because Cardinal Health had actual knowledge of the falsity—no specific intent to defraud the government is required.[22] Cardinal Health's statements

[20] 31 U.S.C. § 3729(a)(1) ("any person who – (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; … is liable to the United States Government ….").

[21] *United States ex rel. Steury v. Cardinal Health, Inc.*, 625 F.3d 262, 267 (5th Cir. 2010).

were material because they had "a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property."[23]

41. While Cardinal Health may not have made an express false statement to the VA when submitting its claim for payment, it is still liable under the False Claims Act because it implicitly certified that it had complied with the relevant contractual requirements.[24] Specifically, Cardinal Health's contract with the VA required it to implicitly certify that the SE infusion pumps were merchantable.[25]

42. The requirement that the SE infusion pumps be merchantable was a material contractual requirement. The VA would not have accepted infusion pumps that were not merchantable—especially infusion pumps that were not merchantable because they injected excessive air into the patients' veins at levels that can kill the patients. Moreover, the VA would not have paid for infusion pumps that it rejected.

43. Every time Cardinal Health delivered an SE infusion pump to the VA and sought payment for the pump, it had to implicitly—and falsely—certify that the SE infusion pump was merchantable. Otherwise, the VA would not accept the SE infusion pump, and would not pay for it. Cardinal Health knew that the SE infusion pumps were not merchantable for the reasons described in this Complaint. By making the implied representation that the SE infusion pump was merchantable, Cardinal Health expected to receive payment from the public treasury for the SE infusion pumps that were not merchantable.

---

[22] *Id*.

[23] *Id*.

[24] *United States v. Science Applications Int'l Corp*., 626 F.3d 1257, 1269 (D.C. Cir. 2010); *United States ex rel. Lemmon v. Envirocare of Utah, Inc*., 614 F.3d 1163, 1169 (10th Cir. 2010); *United States ex rel. Augustine v. Century Health Servs., Inc*., 289 F.3d 409, 415 (6th Cir. 2002).

[25] *See Science Applications Int'l Corp.*, 626 F.3d at 1269); *Envirocare of Utah, Inc*., 614 F.3d at 1169 .

44. Because of the SE infusion pumps' air-in-line defect described above, these implied certifications that Cardinal Health made were false. And Cardinal Health knew they were false because it knew about the SE infusion pumps' air-in-line defect described above. The VA did not know that the SE infusion pumps had the air-in-line defect and that they were not merchantable.

45. Cardinal Health's implied certifications that the SE infusion pumps were merchantable—when, in fact, they were defective and dangerous—had "a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property."[26] This is true for at least two reasons:

a. The VA would not have bought the SE infusion pumps if Cardinal Health had refused to include the warranty of merchantability in the contract;[27] and

b. Under the Federal Acquisition Regulations—which apply to federal purchase contracts throughout the government and to the VA's purchase of the SE infusion pumps—payment is expressly conditioned on the goods being accepted by the government.[28] The government's acceptance is expressly conditioned on the goods "conforming in all respects to contract requirements."[29] Under the Federal Acquisition Regulations, pumps that are not merchantable do not comply with the contract, so they should be rejected. If Cardinal Health had disclosed that its pumps were not merchantable, the VA would not have accepted the pumps—and, therefore, not paid for the pumps—until the defect was corrected and they were merchantable There are only limited exceptions to the VA's ability to accept and pay for goods that do not comply with the contract's requirements. For example, "[i]f the nonconformance is minor," the VA can choose to accept and pay for the goods.[30] And an agency can accept nonconforming goods when there is an exigent circumstance that justifies

[26] *Steury*, 2010 WL 4276073, *3.

[27] *Id*.

[28] *Steury*, 625 F.3d at 269 (citing 48 C.F.R. § 55.212-4(i)).

[29] 48 C.F.R. § 46.407(a) ("The contracting officer should reject supplies or services not conforming in all respects to contract requirements.") (internal citation omitted).

[30] 48 C.F.R. § 46.407(d).

> accepting defective goods.[31] But the agency must expressly make a determination that the circumstances justify taking the goods it knows are defective.[32] Cardinal Health's sale of the SE infusion pumps did not involve circumstances where the government would have paid even if Cardinal Health had told the truth about its defective pumps, instead of falsely certifying that they were merchantable. Instead, if Cardinal Health had disclosed that the pumps were not merchantable, then—under the Federal Acquisition Regulations—the VA would have withheld its acceptance, thus keeping Cardinal Health from being paid. The defect in the pumps was not a "minor" nonconformance that the VA could waive. And because this was a routine purchase of standard medical equipment, the VA had no basis on which to hold that exigent circumstances allowed it to accept nonconforming goods.[33] The pumps might have later been accepted if Cardinal Health were able to fix the defect or provide non-defective pumps that were merchantable. But Cardinal Health would not have been paid on the pumps in the condition that they were supplied.

VI. Prayer

Steury prays that this Court enter a judgment against Cardinal Health for the following:

a. Damages that the government sustained by Cardinal Health's actions;[34]

b. Treble damages;

c. Civil penalties, as authorized by law;

d. Costs of court;

e. Prejudgment and postjudgment interest at the maximum rate allowed by law;

f. Attorneys' fees, to the extent authorized by law; and

g. All other relief, in law or in equity, to which Steury or the United States is entitled.

---

[31] 48 C.F.R. § 46.407(c).

[32] *Id*.

[33] *See* 48 C.F.R. § 46.407(c).

[34] Steury is suing regarding all sales of SE infusion pumps to the VA from October 5, 2001 on.

Respectfully submitted,

/s/ David George
David George
Texas Bar No. 00793212
S.D. Tex. No. 19330
CONNELLY • BAKER • WOTRING LLP
700 JPMorgan Chase Tower
600 Travis Street
Houston, Texas 77002
Telephone: (713) 980-6513
Facsimile: (713) 980-1701

ATTORNEY-IN-CHARGE FOR PLAINTIFF UNITED STATES OF AMERICA *ex rel.* LESLIE STEURY

OF COUNSEL:

David W. Hodges
Texas Bar No. 00796765
S.D. Tex. No. 20460
KENNEDY HODGES LLP
3701 Kirby Drive, Suite 400
Houston, Texas 77098
Telephone: (713) 523-0001
Facsimile: (713) 523-1116

Earnest W. Wotring
Texas Bar No. 22012400
S.D. Tex. No. 15284
CONNELLY • BAKER • WOTRING LLP
700 JPMorgan Chase Tower
600 Travis Street
Houston, Texas 77002
Telephone: (713) 980-1713
Facsimile: (713) 980-1701

October 6, 2011

CERTIFICATE OF SERVICE

I hereby certify that I caused a true and correct copy of the foregoing to be served on all parties of record through this Court's CM/ECF system on October 6, 2011.

Charles Thomas Kruse
BAKER & HOSTETLER LLP
1000 Louisiana Street, Suite 2000
Houston, Texas 77002

/s/ David George
David George